

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte R. MARTIN EMANUELE,
KONSTANTIN G. KOUSOULAS, and
HAMEEDSULTHAN S. ALLAUDEEN

Appeal 2006-3373
Application 09/919,504
Technology Center 1600

Decided: June 19, 2007

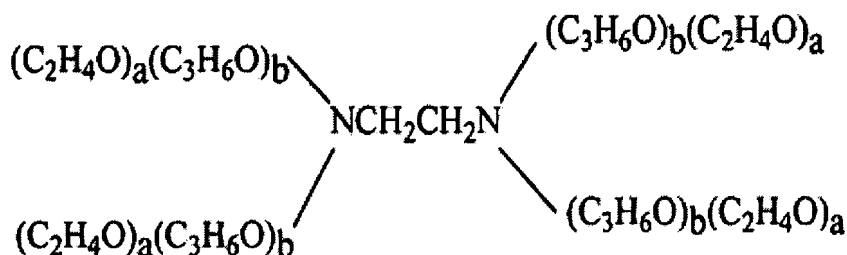
Before DONALD E. ADAMS, DEMETRA J. MILLS, and LORA M.
GREEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-42. We have jurisdiction under 35 U.S.C. § 6(b). Claim 1 is representative of the claims on appeal, and reads as follows:

1. A composition comprising,
one or more nucleic acid sequences selected from the group consisting of oligonucleotides, antisense oligonucleotides, triplex DNA compounds, ribozymes, and mixtures thereof; and
an octablock copolymer, wherein the octablock copolymer has the following formula:



wherein:

the mean aggregate molecular weight of the portion of the octablock copolymer represented by polyoxypropylene is between about 5000 and about 7000 Daltons;

a is a number such that the portion represented by the polyoxyethylene constitutes between about 10% and about 40% of the octablock copolymer by weight; and

b is a number such that the polyoxypropylene portion of the total molecular weight of the octablock copolymer constitutes about 60% and about 90% of the octablock copolymer by weight.

Claims 1-5, 8-13, 16-23, 26-31, 33-36, 38, and 41 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Lemieux.¹ In addition, claims 1, 6, 7, 9, 14, 15, 19, 24, 25, 27, 32, and 37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Lemieux and Emanuele.² Claims 17, 33, 39, 40, and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lemieux. Finally, claims 1-5, 8-

¹ Lemieux, U.S. Patent No. 6,359,054 B1, issued March 19, 2002.

² Emanuele, U.S. Patent No. 5,674,911, issued October 7, 1997.

13, 16-18, 20-22, 28-30, and 34-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kabanov.³

We affirm.

DISCUSSION

The statement of the rejections over the prior art maintained by the Examiner can be found at pages 4-9 of the Examiner's Answer.

Appellants do not argue the merits of the prior art rejections. Rather, Appellants argue "that all of the pending claims of the present application are fully entitled to a priority date of at least October 15, 1993, which renders Lemieux, Emanuele, and Kabanov invalid as §102(b) or §103(a) references." (Br. 14.) Appellants therefore concede the merits of the rejection, and are only arguing that the references relied upon are not prior art. Thus, we focus our analysis on whether the claims on appeal are supported by the 08/138,271 Application, which has a filing date of October 15, 1993.

Appellants assert that "[t]he focus of the '271 application is the introduction of drugs and other therapeutic compounds to the interior of cells." (Br. 14.) According to Appellants, while the '271 Application exemplifies the use of linear polymers to introduce genetic material across cellular membranes and into cells, the disclosure is not limited to their use (*id.*). Appellants argue that they incorporated by reference the polymers taught by Schmolka⁴ and Lundsted,⁵ both of which teach octablock copolymers (Br. 14). Thus, according to Appellants, "the '271 application

³ Kabanov, U.S. Patent No. 5,656,611, issued August 12, 1997.

⁴ Schmolka et al. (Schmolka), "A Review of Block Polymer Surfactants," *J. Am. Oil Chemist Soc.*, Vol. 54, pp. 110-16 (1977)

⁵ Lundsted, U.S. Patent No. 2,674,619, issued April 6, 1954.

clearly teaches polymers as a delivery system to introduce nucleic acid sequences or compounds capable of altering nucleic acid sequence function into cells and methods of delivering these compositions.” (*Id.*)

Lundsted, according to Appellants, was incorporated by reference in accordance with MPEP §608.01(p) at page 15, lines 20-23, and page 17, lines 12-18, thus it was incorporated by reference in its entirety (*id.* at 15). As Lundsted discloses octablock copolymers, and as Lundsted discloses the use of ethylene diamine as the base compounds, Appellants contend that “the claims of the present application are entitled to a priority date of at least October 15, 1993.” (*Id.*) Schmolka, Appellants assert, teaches octablock copolymers including the octablock copolymers disclosed in instant Figure 4 (*id.*). Moreover, Appellants assert, other patents cite Schmolka for its disclosure of octablock copolymers (*id.*).

To perfect their claim for priority under 35 U.S.C. § 120, and thus antedate the teachings of the cited prior art, the '271 application must describe and enable one skilled in the art to make and use the full scope of the presently claimed subject matter. *See In re Scheiber*, 587 F.2d 59, 62, 199 USPQ 782, 784 (CCPA 1978); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991).

In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue. Nonetheless, the disclosure must . . . convey with reasonable clarity to those skilled in the art that . . . [the inventor] was in possession of the invention. Put another way, one skilled in the art, reading the original disclosure, must immediately discern

the limitation at issue in the claims. The inquiry is a factual one and must be assessed on a case-by-case basis.

Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (citations omitted) (alterations in original).

Incorporation by reference provides a method for integrating material from various documents into a host document . . . by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.*

Advanced Display Systems, Inc. v. Kent State University, 212 F.3d 1272, 1282-83, 54 USPQ2d 1673, 1679-80 (Fed. Cir. 2000) (citations omitted) (emphasis added).

The '271 Application discloses that:⁶

The present invention comprises a therapeutic delivery composition effective for treating a disease state comprising an administerable admixture of an effective amount of a therapeutic compound capable of altering nucleic acid sequence function and an effective amount of a surface active nonionic block copolymer having the following general formula:



(*Id.* at 6.)

⁶Note that the panel actually used the Specification of USSN 08/926,297, as that application is a continuation of USSN 08/725,842, which is a continuation of the '271 Application. The Specification of USSN 08/926,297 was used because we could not obtain a copy of the Specification of the '271 Application, but the Specification is assumed to be the same because of the status of the other cited applications as continuations of the '271 Application.

The entire Specification of the '271 Application is drawn to the above linear polymers, and octablock copolymers as instantly claimed are nowhere mentioned in the Specification of the '271 Application. The following are excerpts from the '271 Application, where the Lundsted and Schmolka references are cited. Page 15, lines 9-23, of the '271 Application states (emphasis added):

The polymer blocks are formed by condensation of ethylene oxide and propylene oxide, at elevated temperature and pressure, in the presence of a catalyst. There is some statistical variation in the number of monomer units which combine to form a polymer chain in each copolymer. The molecular weights given are approximations of the average weight of copolymer molecule in each preparation and are dependent on the assay method and calibration standards used. It is to be understood that the blocks of propylene oxide and ethylene oxide do not have to be pure. Small amounts of other materials can be admixed so long as the overall physical properties are not substantially changed. *A more detailed discussion of the preparation of these products [i.e., the linear copolymers $\text{HO}(\text{C}_2\text{H}_4\text{O})_b(\text{C}_3\text{H}_6\text{O})_a(\text{C}_2\text{H}_4\text{O})_b\text{H}$] is found in U.S. Patent No. 2,674,619 [Lundsted], which is incorporated herein by reference in its entirety.*

Page 17, lines 1-18 of the '271 Application states:

A grid illustrating the range of copolymer encompassed by the present invention based upon the molecular weight of the hydrophobe portion and the percent hydrophile, and showing selected nonionic block copolymers appears as Figure 1. The polymer blocks are formed by condensation, at elevated temperature and pressure, of ethylene oxide and propylene oxide in the presence of a catalyst. There is some statistical variation in the number of monomer units which combine to form a polymer chain in each copolymer. The molecular weight given are approximations of the average size of copolymer molecules in each preparation. A further description

of the preparation of these block copolymers [i.e., the linear copolymers $\text{HO}(\text{C}_2\text{H}_4\text{O})_b(\text{C}_3\text{H}_6\text{O})_a(\text{C}_2\text{H}_4\text{O})_b\text{H}$] is found in U.S. Patent No. 2,674,619 [Lundsted]. (Also see, "A Review of Block Polymer Surfactants", Schmolka I.R., *J. Am. Oil Chemist Soc.*, 54:110-116 (1977) and *Block and Graft Copolymerization*, Volume 2, edited by R.J. Ceresa, John Wiley and Sons, New York, 1976[], sic].

Thus, even assuming for the sake of argument that Lundsted and Schmolka were properly incorporated by reference, the disclosure of the '271 Application does not provide written description support of the invention as is now claimed. One skilled in the art reading the above excerpts would only look to Lundsted and Schmolka for their teaching of methods of synthesizing the linear copolymers of formula $\text{HO}(\text{C}_2\text{H}_4\text{O})_b(\text{C}_3\text{H}_6\text{O})_a(\text{C}_2\text{H}_4\text{O})_b\text{H}$, the only block copolymers discussed in the '271 Application. One skilled in the art, reading the above excerpts, would not readily discern that octablock copolymers as claimed in the claims on appeal were part of the invention disclosed in the '271 Application. The Specification of the '271 Application is drawn solely to linear copolymers of formula $\text{HO}(\text{C}_2\text{H}_4\text{O})_b(\text{C}_3\text{H}_6\text{O})_a(\text{C}_2\text{H}_4\text{O})_b\text{H}$, and the references Appellants rely on to show possession of the octablock copolymers were cited only in the context of methods of synthesizing those linear copolymers. Thus, the '271 application thus does not provide written description support for the now claimed invention and Appellants are not entitled to an effective filing date of October 15, 1993. Therefore, the rejections of claims 1-5, 8-13, 16-23, 26-31, 33-36, 38, and 41 under 35 U.S.C. § 102(e) as being anticipated by Lemieux; claims 1, 6, 7, 9, 14, 15, 19, 24, 25, 27, 32, and 37 under

Appeal 2006-3373
Application 09/919,504

35 U.S.C. § 103(a) as being unpatentable over the combination of Lemieux and Emanuele; claims 17, 33, 39, 40, and 42 under 35 U.S.C. § 103(a) as being unpatentable over Lemieux; and claims 1-5, 8-13, 16-18, 20-22, 28-30, and 34-36 under 35 U.S.C. § 103(a) as being unpatentable over Kabanov, are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

John S. Pratt, Esq.
KILPATRICK STOCKTON LLP
1100 Peachtree St
Suite 2800
Atlanta GA 30309-4530